

Appln. No. 08/452,658  
Reply dated March 19, 2004  
Reply to Office Action of 11/07/03

37 C.F.R. §§ 1.136(a) and 1.17(a)(2). With the extension, the time for response is extended up to and including April 7, 2004.

### **REMARKS**

Each of the Examiner's rejections is addressed below.

#### **Claim Rejections**

Claims 31, 33 and 34 are pending in this application. The claims are directed to a method of treating human cancers or tumors by administering to a patient a composition comprising a recombinant IFN- $\beta$  polypeptide produced by a DNA sequence that is operatively linked to an expression control sequence.

Claims 31, 33 and 34 stand provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claim 37 of co-pending patent application 08/253,843 and claims 31, 33 and 34 of co-pending patent application 08/449,930. Applicant agrees to file one or more terminal disclaimers or to cancel or to amend the claims, as appropriate, in this or the co-pending applications to obviate the obviousness-type double patenting rejections upon allowance of any of the conflicting claims.

Claims 31 and 34 stand rejected under 35 U.S.C. § 102(g) as anticipated by Sugano et al. (U.S. Patent 5,514,567) or Sugano et al. (U.S. Patent 5,326,859). According to the Examiner, each Sugano patent discloses a DNA that encodes the amino acid sequence of claim 34 of the instant application. The Examiner also states that the DNA sequence in

each Sugano patent (Table 5) differs by one nucleotide from the DNA claimed in claim 33 of this application. Thus, according to the Examiner, Sugano's DNAs would hybridize to the DNA sequences recited in claim 31. The Examiner further contends that methods taught in each of the Sugano references are embraced by claims 31 and 34 of this application. Applicant traverses. Neither of the Sugano patents anticipates pending claims 31, 33 and 34 of the instant invention.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). *See also Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); Section 2131 of the Manual of Patent Examining Procedure (8th edition, 2003).

The claims of this application are directed to a method of treating human cancers or tumors by administering to a patient a composition comprising a recombinant IFN- $\beta$  polypeptide produced from a DNA that is operatively-linked to an expression control sequence. The Examiner has cited col. 1, lines 10-30 for a supposed teaching of methods of treatment. That section addresses only what the prior art had hoped for for clinical use of native interferons in general.

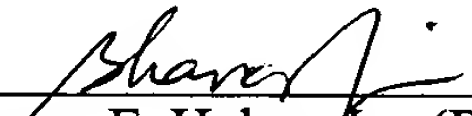
The claimed method is not expressly or inherently described in either of the Sugano patents cited by the Examiner. Each of the Sugano patents is directed to DNA. Further, it was DNA (not the methods of treating human cancers or tumors by the administration of IFN- $\beta$  polypeptides) to which the earlier interference was directed and for

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which priority was determined. 35 U.S.C. §102(g)(1). Accordingly, claims 31, 33 and 34 are not anticipated by the Sugano patents.

For all the above reasons, reconsideration and allowance of the pending claims is requested.

Respectfully submitted,

  
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